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10/595,198	03/30/2006	Claire L. Curl	20498-002US1	4412
<sup>26171</sup> FISH & RICHA	7590 06/02/200 ARDSON P.C.	EXAMINER		
P.O. BOX 1022			CONWAY, THOMAS A	
MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
			2624	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

	Application No.	Applicant(s)			
	10/595,198	CURL ET AL.			
Office Action Summary	Examiner	Art Unit			
	THOMAS A. CONWAY	2624			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>30 Mar</u> This action is <b>FINAL</b> . 2b)⊠ This      Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-33 is/are pending in the application.  4a) Of the above claim(s) is/are withdray  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-33 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or  Application Papers  9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on 22 March 2006 is/are: a Applicant may not request that any objection to the ore Replacement drawing sheet(s) including the correction.	vn from consideration.  relection requirement.  r. a)⊠ accepted or b)□ objected to drawing(s) be held in abeyance. See	37 CFR 1.85(a).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 3/22/06, 01/22/07.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

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#### **DETAILED ACTION**

### Specification

## Content of Specification

Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

1. The disclosure is objected to because of the following informalities: The Brief description of the drawings do not include Figs: 5(A-C), 6(A-D), 7(A-B) or 8(A-B). Appropriate correction is required.

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-5 and 6-11 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent<sup>1</sup> and recent

<sup>1</sup> Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780, 787-88 (1876).

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Federal Circuit decisions<sup>2</sup> indicate that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a particular machine, or (2) transform underlying subject matter (such as an article or material) to a different state or thing. While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform underlying subject matter nor positively tie to a particular machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. Specifically, the claims recite such steps as "determining..., providing..., produce..., multiplied...". However, for example these steps can be performed manually by a human being, and thus would not be tied to a particular machine. The body of the claims must positively recite hardware such as a processor, computer, circuitry, etc, (whatever is disclosed) that is used to perform the steps of the claimed method, and thus tying the claim to a particular machine. Furthermore, nor do the claims appropriately transform the underlying subject matter as required. The claims need to obtain data that represents a physical object, modify/produce calculated information from this data, and finally create an external depiction that represents the modified/produced calculated information/data, (an external depiction, for example, can be but is not limited to visually displaying the modified data/calculated information). Particularly the present claims fail to tie to a particular machine or does not provide for an external depiction. The Examiner makes note that there is mention of a detector but the detector is considered to form part of a preprocessing step and is not significant to the claimed inventive concept. NO NEW MATTER MAY BE ADDED.

 $<sup>^2</sup>$  In re Bilski, 88 USPQ2d 1385 (Fed. Cir. 2008).

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# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 12-13 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nugent et al. (US 6,885,442 B1: hereafter "Nugent").

- 3. **Regarding claims 1, 12 and 23,** Nugent discloses a method, apparatus and computer program for determining the area or confluency of a sample, comprising: providing quantitative phase data relating to the sample and background surrounding the sample (Col. 16, ln 48 Col. 17, ln 7); determining from the quantitative phase data the boundary of the sample (Col. 18, ln 33-43); and determining the area within the boundary in order to determine either the area of the sample or the confluency of the sample (Col. 18, ln 6-9: tomographic plane image; See also Fig. 12).
- 4. **Regarding claims 2, 13 and 24,** Nugent discloses the method, apparatus and computer program of claims 1, 12 and 23, wherein the quantitative phase data is

obtained by detecting light from the sample ("object") by a detector so as to produce differently focused images of the sample (Col. 15, In 14-28), and determining from the different images the quantitative phase data by an algorithm which solves the transport of intensity equation (Eq. 1) so as to produce a phase map of the sample in which the phase data is contained (Fig. 3(f)).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 6-8, 10-11, 17-19, 21-22, 28-30 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nugent in view of Bloem et al. (Fully Automatic Determination of Soil Bacterium Numbers, Cell Volumes, and Frequencies of Dividing Cells by Confocal Laser Scanning Microscopy and Image Analysis, Applied and Environmental Microbiology, Mar. 1995, p. 926-936: hereafter "Bloem").

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6. Regarding claims 6, 17 and 28, Nugent discloses a method, apparatus and computer program of determining the area or confluency of a sample comprising: detecting light emanating from the sample by a detector to form at least two images of the sample which are differently focused to provide two sets of raw data; from the two sets of raw data (Col. 15, In 14-28), determining a quantitative phase map of the sample and its background (Col. 15, In 37-42; See also Fig. 8 (with reference to background)); determining a boundary of the sample from individual phase data values applicable to pixels of the detector which are either above or below a determined pixel value (Col. 4, In 32-41; See also Figs. 12 and 13). Though the calculations used by Nugent details the necessity of matching imaging apertures (Col. 15, In 29-36) and the use of knowledge of the pixel size in the applied array (Col. 14, In 56) in calculating the phase map, which is used in generating area information (Fig. 13) he fails to explicitly disclose determining the area or confluency by multiplying the pixel area by the number of pixels which are either above or below the determined pixel value to thereby determine the area or confluency of the sample.

Bloem discloses determining the area or confluency by multiplying the pixel area by the number of pixels which are either above or below the determined pixel value to thereby determine the area or confluency of the sample (Pg 926, Col. 2, In 1-16). As Bloem mentions, calculating area/confluency of a sample is much improved over visual counting (Pg 926, Col. 2, In 3) when incorporated in a computed environment utilizing information of imaging geometries (pixel size).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the teachings of Nugent, determining the area or confluency by multiplying the pixel area by the number of pixels which are either above or below the determined pixel value to thereby determine the area or confluency of the sample, as suggested by Bloem, as an improvement over visually counting the area of interest.

- 7. **Regarding claims 7, 18 and 29,** Nugent and Bloem disclose the method, apparatus and computer program of claims 6, 17 and 28. Bloem also discloses wherein the pixel values are grey scale values and grey scale values above a determined grey scale value are deemed to be within the sample and are multiplied by the pixel area to determine the area or confluency of the sample (Pg 926, Col. 2, In 4-16).
- 8. **Regarding claims 8, 19 and 30,** Nugent and Bloem disclose the method, apparatus and computer program of claims 6, 17 and 28. Bloem also discloses wherein

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the determined pixel value is determined by identifying the greatest rate of change of grey scale pixel values, thereby identifying the boundary of the sample (Pg 935, Col. 1, Para 1, In 15-20).

- 9. **Regarding claims 10, 21 and 32,** Nugent and Bloem disclose the method, apparatus and computer program of claims 6, 17 and 28. Nugent also discloses wherein the raw data comprises at least one in focus image of the sample and at least one out of focus image of the sample (Col. 15, In 14-28).
- 10. **Regarding claims 11, 22 and 33,** Nugent and Bloem disclose the method, apparatus and computer program of claims 10, 21 and 32. Nugent also discloses wherein the raw data comprises the in focus image of the sample and one positively defocused image and one negatively defocused image of the sample (Col. 15, In 14-28).

Claims 3-5, 9, 14-16, 20, 25-27 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nugent and Bloem in view of Tsujii (US Pub. 2003/0190067 A1).

11. **Regarding claims 3, 14 and 25,** Nugent discloses the method, apparatus and computer program of claims 1, 12 and 23 but fails to disclose wherein the step of

determining the boundary of the sample comprises forming a histogram of quantitative phase data measurements of the sample and background, taking the derivative of the histogram to thereby determine the point of maximum slope of the histogram in the vicinity of the boundary of the sample, and determining a line of best fit on the derivative to obtain a data value applicable to the boundary so that data values either above or below the determined data value are deemed within the sample.

Bloem discloses forming a histogram of quantitative measurements of the sample and background and taking the derivative of the histogram to thereby determine the point of maximum slope of the histogram in the vicinity of the boundary of the sample (Pg 935, Col. 1, Para 1, In 15-20). Segmenting an image using a histogram representing quantitative data of an image in conjunction with threshold derived from the graphic display of the histogram is well known in the art and would be an obvious method of segmenting any type of graphically displayed data representative of a distribution of features. This type of representation would also generate statistical information of a sample under test and allow for quick visual analysis by a human operator.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the steps of Nugent, the forming of a histogram of quantitative phase data measurements of the sample and background, taking the derivative of the histogram to thereby determine the point of maximum slope of the histogram in the vicinity of the boundary of the sample, as suggested by Bloem, as a

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well known method of segmenting an image which would also generate statistical data relevant to a sample as well as allow for a quick visual analysis by a human operator.

Tsujii discloses determining a line of best fit to obtain a data value applicable to the boundary so that data values either above or below the determined data value are deemed within the sample (Para [0057]; See also Fig. 5). Calculating a regression line to fit a slope of a histogram or the results of a manipulated histogram is well known in the art and calculating one with a high confidence level will minimize error in thresholding and subsequently in the segmentation process, resulting in a more accurate segmentation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the steps of Nugent and Bloem, determining a line of best fit to obtain a data value applicable to the boundary so that data values either above or below the determined data value are deemed within the sample, as suggested by Tsujii, as an obvious method of reducing error in segmenting an image.

12. **Regarding claims 4, 15 and 26,** the combination of Nugent, Bloem and Tsujii disclose the method, apparatus and computer program of claims 3, 14 and 25. Bloem also discloses wherein the step of determining the area or confluency comprises determining the area of confluency from the number of data samples which are within the boundary (Pg 926, Col. 2, In 1-16).

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13. **Regarding claims 5**, **16 and 27**, the combination of Nugent, Bloem and Tsujii disclose the method, apparatus and computer program of claims 4, 15 and 26. Bloem also discloses wherein each data sample is applicable to a pixel of a detector and the area of each pixel is known, so that from the known area of the pixels and the number of pixels which register a data value above or below the predetermined data value, the area or confluency of the sample is determined (Pg 926, Col. 2, In 1-16).

14. **Regarding claims 9, 20 and 31,** Nugent and Bloem in combination disclose the method, apparatus and computer program of claims 8, 19 and 30, wherein the greatest rate of change is determined by forming a histogram of grey scale values for all of the pixels which detect the sample and its background, determining the derivative of the histogram to provide a graphical measure of the greatest rate of change of grey scale values at various pixels but fails to teach determining the line of best fit of the curve to determine the grey scale value which defines the boundary of the sample so that all grey scale values which are greater than the determined grey scale value are deemed to be within the sample (see above).

Tsujii discloses determining the line of best fit of the curve to determine the grey scale value which defines the boundary of the sample so that all grey scale values which are greater than the determined grey scale value are deemed to be within the sample (Para [0057]; See also Fig. 5). Calculating a regression line to fit a slope of a histogram or the results of a manipulated histogram is well known in the art and

calculating one with a high confidence level will minimize error in thresholding and subsequently in the segmentation process, resulting in a more accurate segmentation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the steps of Nugent and Bloem, determining the line of best fit of the curve to determine the grey scale value which defines the boundary of the sample so that all grey scale values which are greater than the determined grey scale value are deemed to be within the sample, as suggested by Tsujii, as an obvious method of reducing error in segmenting an image.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS A. CONWAY whose telephone number is (571)270-5851. The examiner can normally be reached on Monday through Friday 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew C Bella/ Supervisory Patent Examiner, Art Unit 2624

/Thomas A. Conway/ Examiner, Art Unit 2624